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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,861	10/20/2004	Yuko Matsumura	P25617	5143

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EXAMINER	
SZPIRA, JULIE ANN	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
09/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/500,861	MATSUMURA ET AL.	
	Examiner	Art Unit	
	JULIE A. SZPIRA	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 6/20/2008. Claims 1-17 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 2, 4-7 and 13-17** rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985).**

Regarding claims 1 and 7, Lipkover discloses an ultrasonic percutaneous (transdermal) penetration device, comprising: a medicine (pharmaceutical agent) containing an active ingredient (column 4, lines 55-56), an irradiation (stimuli transducer) unit that applies ultrasonic waves (column 4, lines 62-64) having a frequency of not less than 0.5 MHz (column 5, lines 24-26) to skin (column 4, lines 65-

67); and a control unit (column 4, lines 68-68; column 5, lines 1-2) that controls irradiation conditions of the irradiation unit, but fails to disclose a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers.

However Shimada et al. teaches a second transducer that produces a separate frequency from the first transducer and a control unit (voltage source) that controls the transducers (column 5, lines 46-53).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second transducer at a different frequency to enhance the delivery of a substance into an area (column 3, lines 31-42).

Regarding claim 2, Lipkover discloses the control unit controlling the frequency, period between on and off of power and irradiation time (column 5, lines 22-27), which are irradiation conditions of ultrasonic waves.

Regarding claim 4, Lipkover discloses wherein the irradiation unit applies not less than two ultrasonic waves (stimulus wave, 5KHz-1MHz and pumping pulses, 50 MHz-300MHz) having different frequencies (column 5, lines 23-32).

Regarding claim 5, Lipkover discloses the irradiation unit applies an ultrasonic wave having a frequency of virtually 1 MHz (column 5, lines 24-25) and an ultrasonic wave having a frequency of not less than 2 MHz (column 5, lines 30-32).

Regarding claim 6, Lipkover discloses a device further comprising a thermal tool (infrared emitter) for warming a portion to be subjected to penetration of the medicine

and a photo stimulator (laser emitter) that applies photic stimulation to the portion to be subjected to penetration of the medicine (column 5, lines 40-48).

Regarding claim 13, Lipkover discloses the medicine is impregnated into a base material (column 4, lines 58-60).

Regarding claim 14, the combination of Lipkover and Shimada as set forth above discloses the method comprising the step of simultaneously as a medicine containing an active ingredient is made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through the medicine (column 9, lines 47-55), and a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers.

Regarding claim 15, the combination of Lipkover and Shimada as set forth above discloses the method comprising the step of after a medicine containing an active ingredient has been made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through a medium that transmits ultrasonic waves (column 6, lines 27-33). Lipkover discloses the first ultrasonic waves stimulating the skin, then the medicine being applied, and then pulses of ultrasonic waves being applied that "pump" the medicine through the skin, which is a medium that transmits ultrasonic waves.

Regarding claim 16, the combination of Lipkover and Shimada as set forth above discloses the method comprising the step of after having applied ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface, a medicine containing an active ingredient is made in contact with the skin to which the ultrasonic

waves have penetrated (column 6, lines 27-33), and a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers.

Regarding claim 17, the combination of Lipkover and Shimada as set forth above discloses the method comprising the steps of the following two processes: a process in which ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface (column 6, lines 27-33); and a process in which, simultaneously as the medicine containing an active ingredient is made in contact with the skin, ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface through the medicine(column 9, lines 47-55), and carrying out the selected processes time-serially in succession, and a second transducer generating waves at a second frequency and the control unit controlling the first and second transducers.

4. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985)** further in view of **Rowe et al. (US 6,234,990 B1).**

Regarding claim 3, Lipkover in view of Shimada et al. disclose the invention substantially as stated above, but fails to disclose a detection unit that detects the depth of a portion for penetration of the medicine, wherein the control unit controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit.

However, Rowe et al. teaches a detection unit (sensor) that detects the depth of a portion for penetration of the medicine, wherein the control unit (controller, 90) controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit (column 12, lines 1-5 and 9-16).

It would have been obvious to one having ordinary skill in the art at the time in the invention was made to provide a depth sensor on the device to allow the medicine to penetrate to the correct depth (column 12, lines 10-12)

5. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985)** further in view of **Kost et al. (US 4,767,402)**.

Regarding claim 8, Lipkover in view of Shimada et al. disclose the invention substantially as stated above, but fails to disclose the frequency of the ultrasonic waves in the range of 3 to 7 MHz.

However, Kost et al. teaches a transdermal drug delivery device with ultrasonic enhancement that operates in the range of 20 kHz (.02 MHz) and 10 MHz (column 4, lines 28-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the range between 3 and 7 MHz, to enhance the transdermal transfer of molecules (column 4, lines 28-31).

6. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al. (US 5,267,985)** in view of **Kost et al. (US 4,767,402)** as applied to claim 8 above, further in view of **Hidaka et al (US 4,990,340).**

Regarding claim 9, Lipkover, Shimada and Kost et al. disclose the invention substantially as stated above, but fails to discloses the active ingredient being selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) glutathione (column 6, lines 62-63; column 9, line 28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use glutathione as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

7. **Claims 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lipkover (US 5,421,816)** in view of **Shimada et al (US 5,267,985)** further in view of **Hidaka et al (US 4,990,340).**

Regarding claim 10, Lipkover in view of Shimada et al. disclose the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of vitamin A, vitamin A acid derivatives, retinol, glutathione, α-hydroxy acid and a cell activation agent.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) vitamin A (column 6, lines 62-63; column 9, line 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use vitamin A as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

Regarding claim 11, Lipkover in view of Shimada et al. disclose the invention substantially as stated above, but fails to disclose the active ingredient being selected from the group consisting of vitamin B group, capsaicin and caffeine.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) capsaicin (column 6, lines 62-63; column 7, line 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use capsaicin as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

Regarding claim 12, Lipkover in view of Shimada et al. disclose the invention substantially as stated above, but fails to discloses the active ingredient being selected from the group consisting of a thiocarbamate-based agent, an imidazole-based agent, an allylamine-based agent, an amorolfine-based agent, an undecylenic acid and derivatives thereof, an antifungal agent and an antitrichophyton agent.

However, Hidaka et al. teaches a transdermal (percutaneous) drug delivery device containing the medicine (drug) an antifungal agent (column 6, lines 62-63; column 8, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an antifungal agent as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

Response to Arguments

8. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie A Szpira/
Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731